

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland

OCT 23 2009

Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: August 7, 2009

Contact: Gerhard Frick

2. Name of the Device:

Microlife Wrist Watch Blood Pressure Monitor, Model BP3BS1-3C

3. Information for the 510(k) Cleared Device (Predicate Device):

a. Microlife Wrist Watch Blood Pressure Monitor, Model BP3MK1-3 (BP W100),
K073398, Microlife Intellectual Property GmbH.

b. Microlife Wrist Watch Blood Pressure Monitor, Model BP3BU1-4U, K061558,
Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Wrist Watch Blood Pressure Monitor, Model BP3BS1-3C is designed to measure systolic and diastolic blood pressure, pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".

The device has an Irregular Heartbeat Detection (IHD) function. It detects the appearance of irregular heartbeat during measurement and the irregular heart beat symbol "⚡" is displayed on the LCD screen if any irregular heart beat signal has been detected. In addition, the device can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer (BPA) software. The

memory data can be transferred to the PC by connecting the monitor with the PC via USB cable.

5. Intended Use:

The Microlife Wrist Watch Blood Pressure Monitor, Model BP3BS1-3C is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist.

The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.

The device can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor with the PC via USB cable.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

The modified device model BP3BS1-3C and the predicate device model BP3MK1-3 (BP W100) use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. Wrist cuff is inflated automatically, deflation rate is controlled by one factory set exhaust valve and the deflation pressures are transferred to one sensor.

The major difference between the two models is the additional feature PC-link function. However, the difference does not affect the accuracy and normal use of this device.

The PC-link function is similar with what is used in the predicate device BP3BU1-4U, which was 510(k) cleared under K061558.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Microlife Wrist Watch Blood Pressure Monitor, Model BP3BS1-3C in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted:

- a. Reliability Test - Storage test
- b. Reliability Test - Operating test
- c. Reliability Test - Vibration test
- d. Reliability Test - Drop test
- e. Reliability Test - Life test
- f. EMC Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that Microlife Wrist Watch Blood Pressure Monitor, Model BP3BS1-3C tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

ANSI/AAMI SP10: 2008 "National Standard for Manual, Electronic or Automated Sphygmomanometers" testing was performed. All relevant sections were addressed and testing conducted. The BP3BS1-3C met all relevant requirements of this standard, as applicable to our modified device.

The BP3BS1-3C is, from a technical point of view, identical to the predicate device, Model BP3MK1-3 (BP W100). Moreover, the measurement algorithm and its program codes of BP3BS1-3C remain unchanged. The fundamental scientific technology of the modified BP3BS1-3C device is the same as the predicate BP3MK1-3 (BP W100) device. Therefore the performance of the BP3BS1-3C in terms of blood pressure measurement would be identical with performance of the predicate BP3MK1-3 (BP W100) device. Repeat clinical testing in accordance with the standard ANSI/AAMI SP10 for the subject BP3BS1-3C device is therefore not necessary as clinical testing results were not affected by the changes to the subject modified device.

9. Software information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". In addition, since our device requires the use of off-the-shelf software to operate the PC-link function, we adhered to the FDA September 1999 document "Guidance for Off-The-Shelf Software Use in Medical Devices".

10. Conclusions:

We have demonstrated that there are no significant differences between the Microlife Wrist Watch Blood Pressure Monitor Model BP3BS1-3C and the predicate devices, Model BP3MK1-3 (BP W100) and Model BP3BU1-4U, in terms of safety and effectiveness based on electrical, mechanical and environmental test results per the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and the ANSI/AAMI Voluntary Standard, SP10: 2008.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

OCT 28 2009

Microlife Intellectual Property Gmbh
C/O Susan D. Goldstein-Falk, MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K092456

Trade/Device Name: Microlife Wrist Watch Blood Pressure Monitor, Model BP3BS1-3C
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Monitor
Regulatory Class: Class II
Product Code: DXN
Dated: September 22, 2009
Received: September 23, 2009

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

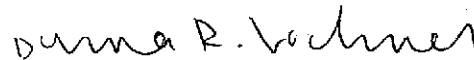
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092456

Device Name: Microlife Wrist Watch Blood Pressure Monitor, Model BP3BS1-3C

Indications For Use:

The Microlife Wrist Watch Blood Pressure Monitor, Model BP3BS1-3C is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist.

The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.

The device can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor with the PC via USB cable.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vachner
(Division Sign-Off)
Division of Cardiovascular Devices

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